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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/734,149

12/15/2003

Michael H. Julius

32388-2038

2082

33721

7590

06/15/2005

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EXAMINER

BELYAVSKIY, MICHAEL A

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/734,149

Applicant(s)

JULIUS ET AL.

Examiner

Michail A. Belyavskyi

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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## DETAILED ACTION

Claims 1-32 are pending.

### *Restriction Requirement*

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
  - I. Claims 1-4, 6, 9, 10, 11, 13, 15, 24-27, 29 and 32 drawn to a method of manufacturing a vaccine, comprising incorporating into said vaccine a polypeptide of **SEQ ID NO:4**, vaccine comprising a polypeptide of SEQ ID NO:4 and a kit for preparation of a vaccination comprising said polypeptide of SEQ ID NO:4 classified in Class 530 subclasses 300 and 350, Class 424 subclass 185.1 and class 435, subclass 810.
  - II. Claims 1-4, 5, 7, 9, 10, 11,12, 14, 15, 24-27, 28, 30 and 32 drawn to a method of manufacturing a vaccine, comprising incorporating into said vaccine a polypeptide of **SEQ ID NO:5**, vaccine comprising a polypeptide of SEQ ID NO:5 and a kit for preparation of a vaccination comprising said polypeptide of SEQ ID NO:5 classified in Class 530 subclasses 300 and 350, Class 424 subclass 185.1 and class 435, subclass 810.
  - III. Claims 1-4, 8, 9, 10, 11,15, 24-27, 31 and 32 drawn to a method of manufacturing a vaccine, comprising incorporating into said vaccine a polypeptide of **SEQ ID NO:6**, vaccine comprising a polypeptide of SEQ ID NO:6 and a kit for preparation of a vaccination comprising said polypeptide of SEQ ID NO:6 classified in Class 530 subclasses 300 and 350, Class 424 subclass 185.1 and class 435, subclass 810.
  - IV. Claims 16-19, 21 and 23, drawn to a method of vaccinating a patient comprising administering an antigen other than CD14 and a polypeptide of **SEQ ID NO:4**, classified in Class 424, subclass 185.1.
  - V. Claims 16-19, 21 and 23, drawn to a method of vaccinating a patient comprising administering an antigen other than CD14 and a polypeptide of **SEQ ID NO:5**, classified in Class 424, subclass 185.1.
  - VI. Claims 16-19, 21 and 23, drawn to a method of vaccinating a patient comprising administering an antigen other than CD14 and a polypeptide of **SEQ ID NO:6**, classified in Class 424, subclass 185.1.

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3. Groups I- VI are different methods. These inventions are different with respect to ingredients, method steps, and endpoints which require non-coextensive searches ; therefore, each method is patentably distinct.
4. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).
6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed.
7. A telephone call was made to John Hunt on 06/03/05 to request an oral election to the above restriction requirement, but did not result in an election being made.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is 571/ 272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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June 13, 2005